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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/977,579 | 10/15/2001 | Peter Cox | 674558-2001 | 1985 |

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| EXAMINER | |
|---|---|
| KOLKER, DANIEL E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/977,579 | COX ET AL. | |
| | Examiner | Art Unit | |
| | Daniel Kolker | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 17, 20, 24 - 29, drawn to nucleic acids, kits, vectors, and host cells, classified in class 435, subclass 69.1, 91.1, 320.1, and 252.3, for example.

II. Claim 18 - 19, drawn to methods of amplifying nucleic acid, classified in class 435, subclass 91.2.

III. Claims 21 – 23, drawn to methods of detecting nucleic acids, classified in class 435, subclass 6.

IV. Claims 30 - 36, drawn to polypeptides, classified in class 530, subclass 350.

V. Claim 37, drawn to a method to screen ligands in a cell-based assay by measuring electrical parameters, classified in class 435, subclass 7.21.

VI. Claim 38, drawn to a method to screen ligands in a cell-free assay by measuring binding, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Invention II do not require the nucleic acids, host cells, or vectors of Invention I. Furthermore, the products of Invention I can be used in a wide variety of processes other than the methods of Invention II. For example, the nucleic acids can be used in hybridization assays, such as Southern blots. Consideration of Inventions I and II together would present a burden because they are classified separately, and would require separate searches. Searching nucleotide sequences involves searching the nucleic acid databases, whereas literature searches would be required to thoroughly evaluate the methods of Invention II. A search for either Invention I or Invention II would not cover the other invention.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Invention I can be used in other processes,

for example in the generation of transgenic or knockout animals. A search for Invention I requires the use of sequence databases, which would not be an effective search for the methods of Invention II.

Inventions I and IV are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotides of Invention I and the polypeptides of Invention IV are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of Groups I and IV together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of Invention I would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group IV. As such, it would be burdensome to search Inventions I and IV together.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant cells of Invention I can be used in other processes, including, for example, the production of recombinant protein for use in cell-free assays. Because the different inventions have different classifications and because a search for the nucleic acid sequences of Invention I would not be useful in determining the patentability of

the screening method of Invention V, a separate search would be required, presenting a serious burden.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids, vectors, and host cells of Invention I cannot be used in the screening assay of Invention VI. Because the different inventions have different classifications and because a search for the nucleic acid sequences of Invention I would not be useful in determining the patentability of the screening method of Invention VI, a separate search would be required, presenting a serious burden.

Invention II is not related to Inventions III, V, or VI because the methods have different goals and require different starting materials and steps. Invention II is a method of amplifying a nucleic acid, but it is not possible to amplify nucleic acid by performing the method of Invention III, because Invention III is a hybridization assay. Furthermore, the method of Invention II cannot be used to detect binding partners, as in Inventions V and VI, because those Inventions require the use of either recombinant cells (Invention V) or protein (Invention VI), neither of which is required for Invention II. Because the methods are completely different and because they have a separate status in the art as indicated by their separate classification, a separate search would be required, presenting a serious burden.

Invention II is not related to Invention IV because the polypeptides of Invention IV cannot be used in the nucleic acid amplification method of Invention II. As detailed above, nucleic acids and polypeptides are chemically distinct entities and cannot be substituted one for the other. Determining the patentability of the polypeptides of Invention IV would require a search of the appropriate databases, which would not be relevant to determining the patentability of the amplification method of Invention II. Therefore a separate search would be required, presenting a serious burden.

Invention III is related to either Invention IV, V, or VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention IV cannot be used in the nucleic acid hybridization assay of Invention III. As detailed above, polypeptides and nucleic acids have distinct chemical structures, and therefore cannot be used interchangeably. The methods of Inventions V and VI

require the use of recombinant cells and polypeptides, neither of which is required for the methods of Invention III. Furthermore, the method steps detailed in Inventions V and VI would be insufficient to carry out the nucleic acid amplification assay of Invention III. Because the inventions are independent and have acquired a separate status in the art as indicated by their separate classification they would each require their own search, presenting a burden for the office.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention IV cannot be used in the method of Invention V, because that method requires a recombinant host cell. Furthermore, the searches for the two inventions would not be coextensive, as the search for the method would require searching patent and non-patent literature, whereas the search for the polypeptides would require searching the appropriate sequence databases. Because the inventions are independent, have acquired a separate status in the art as indicated by their separate classifications, and would require separate searches, consideration of both would present a serious burden.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention IV can be used in other processes, for example they can serve as antigens in the production of antibodies. Furthermore, the searches for the two inventions would not be coextensive, as the search for the method would require searching patent and non-patent literature, whereas the search for the polypeptides would require searching the appropriate sequence databases. Because the inventions are independent, have acquired a separate status in the art as indicated by their separate classifications, and would require separate searches, consideration of both would present a serious burden.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods that require different starting materials and have

different steps. The method of Invention V requires a recombinant host cell, whereas the method of Invention VI requires a polypeptide. The method of Invention V requires measuring an electrical parameter, whereas the method of Invention VI requires measuring binding, which does not have to be by detection of an electrical parameter. Because the methods require different starting materials and have different steps, they would necessitate separate, non-overlapping searches of the literature, presenting a serious burden.

***Requirement for Further Restriction Within Groups I - III***

Applicant's claims are drawn to numerous patentably distinct nucleic acid sequences. If Applicant elects Invention I, II, or III for prosecution, further restriction is required. Applicant must elect a single nucleic acid, identified by SEQ ID NO, to which prosecution will be limited. Each nucleic acid sequence is a patentably distinct product with different physical and functional characteristics. Searching in the databases and considering patentability of more than a single nucleic acid sequence would present a serious burden for the office.

***Requirement for Further Restriction Within Group IV***

Applicant's claims are drawn to numerous patentably distinct polypeptides. If Applicant elects Invention IV for prosecution, further restriction is required. Applicant must elect a single polypeptide, identified by SEQ ID NO, to which prosecution will be limited. Each amino acid sequence is a patentably distinct product with different physical and functional characteristics. Searching in the databases and considering patentability of more than a single amino acid sequence would present a serious burden for the office.

**Applicant is advised that the above requirements are not species elections.**

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHARON L. TURNER, PH.D.
PATENT EXAMINER

Daniel E. Kolker, Ph.D.

12-10-04